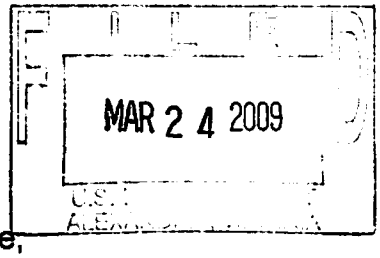
United States Court of Appeals for the Federal Circuit



2008-1352

TRIANTAFYLLOS TAFAS,

Plaintiff-Appellee,

and

SMITHKLINE BEECHAM CORPORATION (doing business as GlaxoSmithKline),
SMITHKLINE BEECHAM PLC, and
GLAXO GROUP LIMITED (doing business as GlaxoSmithKline),

Plaintiffs-Appellees,

v.

JOHN J. DOLL, Acting Under Secretary of Commerce for Intellectual Property
and Acting Director of the United States Patent and Trademark Office,
and UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendants-Appellants.

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Appealed from: United States District Court for the Eastern District of Virginia

Senior Judge James C. Cacheris

United States Court of Appeals for the Federal Circuit

2008-1352

TRIANTAFYLLOS TAFAS,

Plaintiff-Appellee,

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SMITHKLINE BEECHAM CORPORATION (doing business as GlaxoSmithKline),
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v.

JOHN J. DOLL, Acting Under Secretary of Commerce for Intellectual Property
and Acting Director of the United States Patent and Trademark Office,
and UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendants-Appellants.

Appeal from the United States District Court for the Eastern District of Virginia in consolidated case nos. 1:07-CV-846 and 1:07-CV-1008, Senior Judge James C. Cacheris.

DECIDED: March 20, 2009

Before RADER, BRYSON and PROST, Circuit Judges.

Opinion for the court filed by Circuit Judge PROST. Concurring opinion filed by Circuit Judge BRYSON. Opinion concurring in part and dissenting in part filed by Circuit Judge RADER.

PROST, Circuit Judge.

The United States Patent and Trademark Office ("USPTO") appeals the April 1, 2008 decision of the United States District Court for the Eastern District of Virginia granting summary judgment that four recently promulgated rules exceed the scope of

the USPTO's rulemaking authority. Because we conclude that the four rules are procedural, but that Rule 78 is inconsistent with 35 U.S.C. § 120, we affirm-in-part, vacate-in-part, and remand.

I. BACKGROUND

In January 2006, the USPTO initiated two related notice and comment rulemaking proceedings. After receiving and considering the public comments, the USPTO issued the new rules on August 21, 2007, with an effective date of November 1, 2007. Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46,716 (Aug. 21, 2007). Four of the new rules (collectively, the "Final Rules") are at issue in this appeal.

Two of the new rules, Final Rule 78 and Final Rule 114, pertain to continuation applications and requests for continued examination ("RCEs") and were issued to address the "large and growing backlog of unexamined patent applications." Id. at 46,717. Final Rule 78 governs the availability of continuation and continuation-in-part applications.[1] Under the rule, an applicant is entitled to file two continuation applications as a matter of right. 37 C.F.R. § 1.78(d)(1)(i). If an applicant wishes to pursue more than two continuation applications, he must file a petition "showing that the amendment, argument, or evidence sought to be entered could not have been submitted during the prosecution of the prior-filed application." Id. § 1.78(d)(1)(vi). If the applicant cannot make the requisite showing, the USPTO will accept the application

[1] For a discussion of the problems created by continuation applications, see Mark A. Lemley & Kimberly A. Moore, Ending Abuse of Patent Continuations, 84 B.U. L. Rev. 63, 71-83 (2004).

for examination but will "refuse to enter, or will delete if present, any specific reference to a prior-filed application." Id. § 1.78(d)(1). The effect of this is to remove the application from the scope of 35 U.S.C. § 120, which would otherwise entitle the application to the filing date of the prior-filed application. Final Rule 114 provides for similar treatment of RCEs. Under the rule, an applicant is allowed one RCE as a matter of right. Id. § 1.114(f). For each additional RCE, the applicant must file a petition "showing that the amendment, argument, or evidence sought to be entered could not have been submitted prior to the close of prosecution in the application." Id. § 1.114(g). The limitation on RCEs is applied on the basis of application families, rather than individual applications. Id. § 1.114(f).

The two other rules, Final Rule 75 and Final Rule 265, are intended to address the USPTO's difficulty in examining applications that contain a large number of claims. 72 Fed. Reg. at 46,721. Final Rule 75 requires an applicant who submits either more than five independent claims or twenty-five total claims to provide the examiner with information in an examination support document ("ESD"). 37 C.F.R. § 1.75(b)(1). The requirements for ESDs are set forth in Final Rule 265. To comply with Final Rule 265, an applicant must conduct a preexamination prior art search, provide a list of the most relevant references, identify which limitations are disclosed by each reference, explain how each independent claim is patentable over the references, and show where in the specification each limitation is disclosed in accordance with 35 U.S.C. § 112, ¶ 1. Id. § 1.265(a).

Shortly after the Final Rules were published in the Federal Register, Triantafyllos Tafas, SmithKline Beecham Corporation, and Glaxo Group Limited (collectively,

"Appellees") filed suit against the USPTO. On October 31, 2007, the district court preliminarily enjoined enforcement of the Final Rules. Tafas v. Dudas, 511 F. Supp. 2d 652 (E.D. Va. 2007) ("Tafas I"). Appellees then moved for summary judgment that the Final Rules are invalid and sought a permanent injunction against their enforcement. Appellees' summary judgment motions alleged that the Final Rules were impermissibly substantive, inconsistent with law, arbitrary and capricious, incomprehensibly vague, impermissibly retroactive, and procedurally defective.

The district court agreed with Appellees that the Final Rules were "substantive rules that change existing law and alter the rights of applicants such as [Appellees] under the Patent Act." Tafas v. Dudas, 541 F. Supp. 2d 805, 814 (E.D. Va. 2008) ("Tafas II"). Specifically, the district court found that the Final Rules created limits on continuation applications, RCEs, and claims that were inconsistent with several sections of the Patent Act, as well as precedent from this court and its predecessor, the Court of Customs and Patent Appeals. The district court concluded that because the USPTO lacks substantive rulemaking authority under Merck & Co., Inc. v. Kessler, 80 F.3d 1543, 1550 (Fed. Cir. 1996), the Final Rules exceed the USPTO's statutory jurisdiction in violation of 5 U.S.C. § 706(2). Tafas II, 541 F. Supp. 2d at 814. Accordingly, the district court granted Appellees' motion for summary judgment that the Final Rules are invalid.[2]

[2] The district court fully disposed of the case on the grounds that the Final Rules are substantive. As part of its analysis, the court partially considered whether the rules conflict with the law. Apart from this, the court did not address Appellees' other arguments.

The USPTO timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

"We review the district court's grant of summary judgment without deference, reapplying the same standard as the district court." Star Fruits S.N.C. v. United States, 393 F.3d 1277, 1281 (Fed. Cir. 2005). Summary judgment is appropriate only if the record shows "there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); see also Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986). Under the Administrative Procedure Act ("APA"), the reviewing court shall set aside agency action if it is found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "contrary to constitutional right, power, privilege, or immunity," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A)-(D).

The USPTO alleges two main errors in the district court's analysis. First, the USPTO argues that the court erred by failing to give the agency's interpretation of 35 U.S.C. § 2(b)(2)'s grant of rulemaking authority proper deference under Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). The USPTO contends that under a proper application of Chevron, the inquiry in this case is not whether the rules are substantive or procedural, but whether they fit within a reasonable interpretation of § 2(b)(2), which gives the USPTO authority to "establish regulations, not inconsistent with law, which . . . shall govern the conduct of proceedings in the Office . . . [and] facilitate and expedite the processing of patent

applications." 35 U.S.C. § 2(b)(2). Second, the USPTO argues that even if the substantive/procedural framework is applicable, the Final Rules are clearly procedural. According to the USPTO, the district court's erroneous conclusion that the Final Rules are substantive was the result of a mistaken interpretation of the rules, misapplication of the statutes and precedent, and failure to properly give deference to the USPTO's interpretation of the Patent Act under Chevron and National Cable & Telecommunications Ass'n v. Brand X Internet Services, 545 U.S. 967 (2005). We address each argument in turn.

A. The Scope of the USPTO's Rulemaking Authority

Section 2(b)(2) of the Patent Act gives the USPTO authority to

> establish regulations, not inconsistent with law, which . . . (A) shall govern the conduct of proceedings in the office; . . . (C) shall facilitate and expedite the processing of patent applications, particularly those which can be filed, stored, processed, searched, and retrieved electronically . . . (D) may govern the recognition and conduct of agents, attorneys, or other persons representing applicants or other parties before the Office . . . .

35 U.S.C. § 2(b)(2). Additionally, 35 U.S.C. § 132(b) requires the USPTO to "prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant." The USPTO asserts that this case should be fully resolved in its favor based on the language of these two sections. So long as the Final Rules fall within the scope of either § 2(b)(2) or § 132(b), the USPTO contends, they do not exceed its rulemaking authority. Further, the USPTO argues that this court has previously recognized that the USPTO's interpretation of its rulemaking authority under § 2(b)(2) is entitled to Chevron deference. See, e.g., Lacavera v. Dudas, 441 F.3d 1380, 1383 (Fed. Cir. 2006), cert. denied, 127 S. Ct. 1246 (2007). The USPTO thus argues that the district court erred by grafting a distinction between substantive and

procedural rules onto the plain language of § 2(b)(2) without according any deference to the USPTO's interpretation. Appellees maintain that the district court correctly decided that the USPTO cannot make substantive rules and no deference is due until it is established that the USPTO has acted within its statutory authority. We begin by addressing whether the USPTO's authority is subject to the substantive/procedural distinction, and then examine the proper level of deference to be given in this case.

1. The Substantive/Procedural Distinction

We agree with the district court that § 2(b)(2) "does not vest the USPTO with any general substantive rulemaking power." Tafas II, 541 F. Supp. 2d at 811. This principle is amply supported by our precedent. See, e.g., Animal Legal Def. Fund v. Quigg, 932 F.2d 920, 930 (Fed. Cir. 1991) ("A substantive declaration with regard to the Commissioner's interpretation of the patent statutes, whether it be section 101, 102, 103, 112 or other section, does not fall within the usual interpretation of [the language in section 6, the predecessor of § 2(b)(2)]."); Merck, 80 F.3d at 1550 (Section 6 "does NOT grant the Commissioner the authority to issue substantive rules. Because Congress has not vested the Commissioner with any general substantive rulemaking power, the Final Determination at issue in this case cannot possibly have the force and effect of law." (citations and quotation marks omitted)); Cooper Techs. Co. v. Dudas, 536 F.3d 1330, 1335 (Fed. Cir. 2008) ("To comply with section 2(b)(2)(A), a Patent Office rule must be 'procedural'—i.e., it must 'govern the conduct of proceedings in the Office.'").

Additionally, when Merck was decided, 35 U.S.C. § 6(a) gave the USPTO authority to establish regulations that govern "the conduct of proceedings." We agree

with Appellees that Congress's decision to replace § 6(a) with the current § 2(b)(2), which contains the same grant of authority to regulate "the conduct of proceedings in the Office" is indicative that Congress did not intend to give the USPTO substantive rulemaking authority.[3] See Lorillard v. Pons, 434 U.S. 575, 580 (1978) ("Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change.").

Accordingly, we must reject the USPTO's argument that the substantive/procedural distinction is immaterial in this case.

2. Chevron Deference

The USPTO argues that the district court erred by failing to accord Chevron deference at two stages of its analysis. First, Chevron deference is allegedly required for the threshold question of whether § 2(b)(2) vests the USPTO with substantive rulemaking authority. Second, the USPTO maintains that its interpretation of various sections of the Patent Act, and its accordant belief that the Final Rules are consistent therewith, is also entitled to deference. We cannot accept the USPTO's first argument, but we conclude that the USPTO's interpretations of statutes that pertain to the USPTO's delegated authority are entitled to Chevron deference.

Before a reviewing court grants Chevron deference, it must first determine whether the agency's interpretation of the statute was made pursuant to "a

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[3] While Cooper Technologies, 536 F.3d at 1336-37, casts doubt on the district court's view that § 2(b)(2)(B) requires notice and comment rulemaking for all USPTO rules, we nevertheless agree that Congress did not hide the "elephant" of substantive rulemaking authority in the "mousehole" of § 2(b)(2)(B). See Tafas II, 541 F. Supp. 2d at 812; see also Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 468 (2001).

congressional delegation of administrative authority." Adams Fruit Co. v. Barrett, 494 U.S. 638, 649 (1990). This threshold inquiry, which has been dubbed Chevron "step zero," determines "whether courts should turn to the Chevron framework at all." Thomas W. Merrill & Kristin E. Hickman, Chevron's Domain, 89 Geo. L.J. 833, 836 (2001). Cases from this court have concluded, in different circumstances, that an agency's determination of the scope of its own authority is not entitled to Chevron deference. See, e.g., Borlem S.A.-Empreedimentos Industriais v. United States, 913 F.2d 933, 937 (Fed. Cir. 1990) ("A court is indeed obligated to give deference to an agency acting within its scope of responsibility. . . . [However,] such deference should not apply when the issue is the legal scope of an agency's authority."). A majority of the Supreme Court has not yet spoken to this issue. Cf. Miss. Power & Light Co. v. Miss. ex rel. Moore, 487 U.S. 354, 380 (1988) (Scalia, J., concurring) ("Contrary to the dissent, we have held that this rule of deference applies to an agency's interpretation of a statute designed to confine its authority." (citation omitted)) with id. at 386 (Brennan, J., dissenting) ("I cannot, however, agree with Justice SCALIA's conclusion that courts must defer to an agency's statutory construction even where, as here, the statute is designed to confine the scope of the agency's jurisdiction to the areas Congress intended it to occupy."); see also N. Ill. Steel Supply Co. v. Sec'y of Labor, 294 F.3d 844, 846-47 (7th Cir. 2002) (recognizing Justice Scalia's concurrence in Mississippi Power, stating that "the Supreme Court has not definitively ruled on the issue," and declining to grant deference to the agency's determination of its own jurisdiction).

We are not persuaded by the USPTO's arguments in this case that Chevron deference should be extended to the issue of whether § 2(b)(2) provides substantive

rulemaking authority. To the extent the USPTO relies on Federal Circuit cases that give Chevron deference to the USPTO's interpretation of certain phrases present in § 2(b)(2), we conclude that those cases are inapposite because they involve judicial review of rules that are procedural, and thus within the judicially interpreted scope of the USPTO's rulemaking authority. See, e.g., Bender v. Dudas, 490 F.3d 1361, 1368 (Fed. Cir. 2007) (deferring to the USPTO's interpretation of the phrase "before the Office" on review of the USPTO's decision to discipline an attorney for misconduct); Lacavera, 441 F.3d at 1383 (deferring to the USPTO's interpretation of "necessary qualifications" to be required of individuals who seek recognition to practice before the USPTO); Stevens v. Tamai, 366 F.3d 1325, 1333-34 (Fed. Cir. 2004) ("In view of the reasonableness of the Office's rules governing the procedure in patent interferences, and the substantial deference we accord such rules . . . ." (emphasis added)). Because we decline to accord deference with respect to the question of whether the USPTO has substantive rulemaking authority, our conclusion above that the USPTO does not have such authority is unaffected by Chevron.

The next question is the level of deference to be given to USPTO rules that are within the scope of the USPTO's delegated authority, i.e., procedural rules promulgated under § 2(b)(2) or § 132(b). Our precedent is clear that the Chevron framework is applicable to review of these rules. See, e.g., Cooper Techs., 536 F.3d at 1337; Bender, 490 F.3d at 1368; Lacavera, 441 F.3d at 1383; Stevens, 366 F.3d at 1333; Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1425 (Fed. Cir. 1988). Thus, on review of a procedural rule that has been issued by the USPTO, we will give Chevron deference to the USPTO's interpretation of statutory provisions that relate to the exercise of

delegated authority. See Cooper Techs., 536 F.3d at 1337 ("Because the Patent Office is specifically charged with administering statutory provisions relating to 'the conduct of proceedings in the Office,' 35 U.S.C. § 2(a)(2)(A), we give Chevron deference to its interpretations of those provisions.").

B. Classification of the Final Rules

With the analytical framework established, we turn to whether the Final Rules are substantive or procedural. The parties agree that the USPTO has authority under § 2(b)(2) to promulgate procedural rules. They vigorously disagree, however, as to how the boundary between "substantive" and "procedural" rules should be defined.

The district court relied on Chrysler Corp. v. Brown, 441 U.S. 281, 302 (1979), to define as substantive "any rule that 'affect[s] individual rights and obligations.'" Tafas II, 541 F. Supp. 2d at 814. We do not read Chrysler to create such a broad and absolute rule. In the portion of Chrysler cited by the district court, the Court simply "noted a characteristic inherent in the concept of a 'substantive rule'" and identified "an important touchstone for distinguishing those rules that may be 'binding' or have the 'force of law.'" 441 U.S. at 302. Substantive rules certainly "affect individual rights and obligations," but that inquiry does not necessarily distinguish most procedural requirements, which will also "affect individual rights and obligations." The Supreme Court itself made this observation when drawing the line between "substance" and "procedure" in the context of the Rules Enabling Act. See Hanna v. Plumer, 380 U.S. 460, 464-65 (1965) ("Undoubtedly most alterations of the rules of practice and procedure may and often do affect the rights of litigants."). This court's predecessor made the same observation. See In re Van Ornum, 686 F.2d 937, 945 (CCPA 1982)

("True, the rule is substantive in that it relates to a condition under which a patent will be granted which otherwise would have to be denied for double patenting. Much of the content of the PTO rules is 'substantive' in this respect."). While this court has previously evaluated USPTO rules in terms of whether they "affect individual rights and obligations," it has done so in the process of distinguishing between "interpretive" and "substantive" rules. See Animal Legal Def. Fund, 932 F.2d at 927; Cooper Techs., 536 F.3d at 1336. We agree, therefore, with the USPTO that while the inquiry set forth in Chrysler and used in Animal Legal Defense Fund and Cooper Technologies may be useful in defining the boundary between interpretive and substantive rules, it is not dispositive on the issue of whether the Final Rules are procedural.

In addition to Chrysler, the parties cite several cases from the D.C. Circuit that have addressed the boundaries of substantive rules.[4] In American Hospital Ass'n v. Bowen, the D.C. Circuit defined substantive rules, as contrasted with interpretive rules, as those which "grant rights, impose obligations, or produce other significant effects on private interests, or which effect a change in existing law or policy." 834 F.2d 1037, 1045 (D.C. Cir. 1987) (citations and quotation marks omitted). With respect to the distinction between procedural and substantive rules, Bowen suggested that substantive rules "encode[] a substantive value judgment or put[] a stamp of approval or

[4] The concurrence and dissent each correctly point out that this is not a case arising under the notice and comment rulemaking provision of the APA. Therefore, this case does not turn on whether the rules are "procedural" within the meaning of 5 U.S.C. § 553(b)(A). We recognize that the definitions of "substance" and "procedure" in the notice and comment rulemaking context may embody policy considerations that are not coextensive with the considerations at issue in this case. However, we find that these cases are nevertheless helpful to the task of drawing a similar line between "substance" and "procedure" in the present case.

disapproval on a given type of behavior." Id. at 1047. However, the D.C. Circuit has also noted that, "[o]f course, procedure impacts on outcomes and thus can virtually always be described as affecting substance." JEM Broad. Co. v. FCC, 22 F.3d 320, 326 (D.C. Cir. 1994) (quoting Air Transp. Ass'n of Am. v. Dep't of Transp., 900 F.2d 369, 383 (D.C. Cir. 1990) (Silberman, J., dissenting)). Similarly, the D.C. Circuit held in Public Citizen v. Department of State that although the State Department's decision not to search documents produced after the date of a Freedom of Information Act request represented a "judgment about procedural efficiency," such a judgment does not "convert a procedural rule into a substantive one." 276 F.3d 634, 641 (D.C. Cir. 2002) (quotation marks omitted). Thus, the D.C. Circuit has considered many of the issues underlying the present case and has understandably hesitated to adopt a conclusive test for when rules cross the line between procedure and substance.

We are most persuaded in this case by the D.C. Circuit's approach in JEM. At issue in that case were "hard look" rules adopted by the Federal Communications Commission ("FCC") in response to a significant number of "carelessly prepared and speculative applications" for broadcasting licenses. 22 F.3d at 327. Under those rules, applications that either failed to include necessary information or contained incorrect or inconsistent information that could not be "resolved within the confines of the application and with a high degree of confidence" were dismissed with no opportunity to cure the defect. Id. at 322. The D.C. Circuit rejected JEM's contention that the rules were substantive because they "deprive[d] license applicants of the opportunity to correct errors or defects in their filings." Id. at 327. In doing so, the court noted that a "critical feature of the procedural exception [in section 553 of the APA] is that it covers

agency actions that do not themselves alter the rights or interests of parties, although [they] may alter the manner in which the parties present themselves or their viewpoints to the agency." Id. at 326 (emphasis added) (quotation marks omitted). The "critical fact" that was "fatal to JEM's claim," the court held, was that the "hard look" rules "did not change the substantive standards by which the FCC evaluates license applications." Id. at 327. The court recognized that the rules could result in the loss of substantive rights, but found that they were nonetheless procedural because they did not "foreclose effective opportunity to make one's case on the merits." Id. at 327-28 (quoting Lamoille Valley R.R. Co. v. Interstate Commerce Comm'n, 711 F.2d 295, 328 (D.C. Cir. 1983)).

While we do not purport to set forth a definitive rule for distinguishing between substance and procedure in this case, we conclude that the Final Rules challenged in this case are procedural. In essence, they govern the timing of and materials that must be submitted with patent applications. The Final Rules may "alter the manner in which the parties present . . . their viewpoints" to the USPTO, but they do not, on their face, "foreclose effective opportunity" to present patent applications for examination. JEM, 22 F.3d at 326, 328.

Final Rules 78 and 114 provide requirements for when continuation applications will be accepted and RCEs will be granted. The D.C. Circuit has recognized time schedules as being "definitely at the procedural end of a spectrum running from 'procedural' to 'substantive.'" Lamoille, 711 F.2d at 328. Applicants who include in each continuation application all amendments, arguments, and evidence available at the time of filing will not be limited by Final Rule 78. Similarly, applicants who diligently

present all of their amendments, arguments, and evidence as soon as possible during prosecution will be granted as many RCEs as they require. Thus, applications that are submitted in compliance with these timing requirements will be fully examined and given all of the benefits provided by the Patent Act. See JEM, 22 F.3d at 327. We do not believe that requiring applicants to raise all then-available amendments, arguments, and evidence by the second continuation application or the first RCE is so significant a burden that applicants will be effectively foreclosed from obtaining the patent rights to which they are entitled. See Lamoille, 711 F.2d at 328.

We are of course aware that the impact of Final Rules 78 and 114 will be largely dependent on how the USPTO interprets when amendments, arguments, and evidence "could not have been submitted during the prosecution of the prior-filed application" or "prior to the close of prosecution." 37 C.F.R. §§ 1.78, 1.114(g). When the Final Rules were published, the USPTO also published responses to questions raised during the notice and comment proceedings, many of which addressed specific scenarios under which continuation applications and RCEs may be requested. See, e.g., 72 Fed. Reg. at 46,769-77. The district court relied on the contents of these responses to conclude that the USPTO "intends to deny additional applications in almost all circumstances" such that Final Rules 78 and 114 are in fact "hard limits" on continuation applications and RCEs. Tafas II, 541 F. Supp. 2d at 814-16. Appellees and several amici encourage us to adopt this analysis. However, we decline to rely on these responses, which are not binding on the USPTO and often either state that decisions will be made on a "case-by-case basis" or speak in terms of whether it is "likely" or "unlikely" that a petition will be granted, to justify a decision that the Final Rules, as actually codified in

the Code of Federal Regulations, are facially invalid. These responses are not binding on the courts, which will be free to entertain challenges to the USPTO's application of the Final Rules, including its view of when amendments, arguments, and evidence could not have been submitted earlier, under the standard set forth in 5 U.S.C. § 706.

With respect to the ESD requirement, Final Rules 75 and 265 require applicants who present more than five independent claims or twenty-five total claims to provide the examiner with information about the prior art and why they believe the claims are patentable over it. Once a satisfactory ESD is submitted, examination will proceed in precisely the same manner as it would have in the absence of the rule. It is important to note that an examiner is not permitted to substantively reject claims on grounds that the ESD did not prove that the claims are patentable. While an examiner is of course free to base a rejection on references disclosed in the ESD, he must nevertheless set forth his own prima facie case of unpatentability. Thus, while the rule may put a burden of production on the applicant, the examiner maintains the burden of persuasion.

This court has previously recognized the validity of two USPTO rules that place upon applicants the burden of submitting information in response to an examiner's request. See Star Fruits, 393 F.3d at 1282-84 (Rule 105); see also In re Epstein, 32 F.3d 1559, 1570 (Fed. Cir. 1994) (Plager, J., concurring) (Rule 56). Rather than arguing that Rules 56 and 105 are invalid, Appellees attempt to distinguish them from the Final Rules because they only pertain to information that is already known by or readily available to the applicant. GlaxoSmithKline Br. 48. While we recognize this difference, we decline to draw the line between procedure and substance on these grounds alone. A procedural rule does not become substantive simply because it

requires the applicant to exert more effort to comply, so long as the effort required is not so great that it effectively forecloses the possibility of compliance. See Lamoille, 711 F.2d at 328.

Appellees and amici argue that the ESD requirement is in fact so draconian that compliance would be both impossible and extraordinarily foolish. With respect to impossibility, Appellees argue that Rule 265 requires a "world-wide search of prior art without regard to scope, time, or cost." GlaxoSmithKline Br. 46. We do not find such a requirement on the face of Final Rule 265. Rather, the rule describes a preexamination search of "U.S. patents and patent application publications, foreign patent documents, and non-patent literature," and requests specific details about the scope of the search. 37 C.F.R. § 1.265(a)-(b). The text of the rule does not demand that the applicant review every reference that fits into one of those categories, regardless of its location or accessibility. Instead, it requires applicants to conduct and document a "search." A "search" of "non-patent literature" does not necessarily require a visit to every library in every corner of the world. A reasonable, cost-effective search is just as much a "search" as the search described by Appellees. While the text of the rules sets forth a facially reasonable procedural requirement,[5] we are mindful of the possibility that the USPTO may in some cases attempt to apply the rules in a way that makes compliance essentially impossible and substantively deprives applicants of their rights. In such cases, judicial review will be available under 5 U.S.C. § 706.

[5] To the extent the USPTO has commented about its intended application of the ESD requirement, either in public speeches or in the Federal Register, we make the same observation made above: these comments do not bind the USPTO with respect to its future actions, and they do not affect the courts' ability to resolve challenges to specific applications of the rules.

Search scope aside, several amici argue that submitting an ESD is so wrought with peril that sane applicants will be absolutely limited to five independent claims and twenty-five total claims. These arguments have two components. The first is that even the most diligently prepared ESD will inevitably open the applicant to inequitable conduct allegations that will entail costly litigation and a possible finding of unenforceability. We believe this concern is too speculative to void the rules and, in any event, is at its core a matter of inequitable conduct doctrine, not USPTO rulemaking authority. The reach of inequitable conduct is solely within the control of the courts, and the doctrine has obviously not yet been applied in the context of an ESD. We decline to decide that an otherwise valid USPTO rule that requires applicants to provide information is void because this court might in the future apply inequitable conduct doctrine in such a way that honest applicants who comply in good faith will nevertheless lose their patent rights. Under Kingsdown Medical Consultants, Ltd., v. Hollister, Inc., "'gross negligence' does not of itself justify an inference of intent to deceive." 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc in relevant part). We recognize that the drafting of an ESD will entail browsing many references, that mistakes and omissions will inevitably occur, and that the courts will be asked to determine if there was inequitable conduct. However, doubt about the judiciary's ability to apply its own doctrine in a way that yields fair results and discourages frivolous allegations should not preclude the USPTO from promulgating rules that are within its statutory authority.

Second, several amici argue that ESDs will decrease the value of patent rights because the statements therein will limit claim scope through prosecution history estoppel. We do not believe applicants have a right to remain silent throughout

prosecution in order to maximize their advantage in later litigation. The Patent Act demonstrates that applicants are expected to be forthright about their inventions. Section 112 requires applicants to provide a "written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same." 35 U.S.C. § 112, ¶ 1 (emphasis added). It also requires the application to "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." Id. § 112, ¶ 2 (emphasis added). This court has recognized that "[a]pplicants for patents have a duty to prosecute patent applications in the Patent Office with candor, good faith, and honesty." See Honeywell Int'l Inc. v. Universal Avionics Sys. Corp., 488 F.3d 982, 999 (Fed. Cir. 2007). We are aware that some applicants attempt to say as little as possible during prosecution so that the precise boundaries of their claims will be open to argument as competitors' products enter the market and new prior art references are found during litigation. However, we consider this practice to be a burden on the patent system, not a right that can be invoked to void the Final Rules.

Having concluded our discussion of why the Final Rules are procedural, it is important to note one way in which our substantive/procedural analysis differs from that of the district court. While the district court initially stated that it need not decide "whether the Final Rules run contrary to the Act's provisions," it did just that throughout its discussion of the substantive nature of the rules. Tafas II, 541 F. Supp. 2d at 811 n.4, 814-17. The district court in large part based its conclusion that the Final Rules are substantive on grounds that they deprived applicants of rights guaranteed by various

sections of the Patent Act. Id. at 814-17. Because, as discussed above, we do not believe the test the district court distilled from Chrysler—whether the rules "affect individual rights and obligations"—is correct, we similarly conclude that consistency with the Patent Act is not the touchstone of whether the rules are procedural or substantive. For example, 37 C.F.R. § 1.52(a)(1)(i) requires most documents submitted to the USPTO to be printed on white paper. No one would dispute that this rule is procedural. If Congress then created a new section of the Patent Act that required all documents to be printed on yellow paper, § 1.52(a)(1)(i) would certainly become invalid. However, the reason for its invalidity would be that it is inconsistent with an express provision of the Act, not that the new statute transformed it from a procedural rule into a substantive one. Similarly, the USPTO's "determination" at issue in Merck was found to be substantive without regard to whether it conflicted with existing law. See 80 F.3d at 1550. Therefore, we find it necessary to separate the question of whether the Final Rules are procedural from the question of their consistency with the Patent Act. Having addressed the former, we now turn to the district court's view of the latter.

C. Consistency with the Patent Act

We address here the specific conflicts that the district court identified and relied upon in its opinion. Because each of the rules is procedural, we must, as discussed above, give Chevron deference to the USPTO's interpretation of the provisions of the Patent Act that relate to "proceedings in the Office." Cooper Techs., 536 F.3d at 1337. For such provisions, we must first determine "whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously

expressed intent of Congress." Chevron, 467 U.S. at 842-43. "[I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." Id. at 843. Even if a court has previously resolved the specific question at issue, the agency's construction must be adopted unless "the prior court decision holds that its construction follows from the unambiguous terms of the statute and thus leaves no room for agency discretion." Brand X, 545 U.S. at 982.

1. Final Rule 78

The district court found that Final Rule 78's requirement for the third and subsequent continuation applications was inconsistent with the text of 35 U.S.C. § 120 and this court's precedent. Section 120, with emphasis and bracketed enumeration added, provides that:

> An application for patent for [1] an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is [2] filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, [3] if filed before the patenting or abandonment of or termination of proceedings on [3a] the first application or on [3b] an application similarly entitled to the benefit of the filing date of the first application and [4] if it contains or is amended to contain a specific reference to the earlier filed application. No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section.

The district court concluded that Final Rule 78 was inconsistent with the statutory mandate that qualifying applications "shall have" the benefit of the priority date of the

initial application. Tafas II, 541 F. Supp. 2d at 814. Additionally, the district court cited this court's predecessor for the propositions that "there is no statutory basis for fixing an arbitrary limit to the number of [continuing] applications," id. (quoting In re Henriksen, 399 F.2d 253, 254 (CCPA 1968)) (alteration provided by the district court), and that "a limit upon continuing applications is a matter of policy for the Congress," id. (quoting In re Hogan, 559 F.2d 595, 604 n.13 (CCPA 1977)). In light of the USPTO's presumed "inten[t] to deny additional applications in almost all circumstances," the district court found that Final Rule 78 set forth a "mechanical rule" that "changes existing law and deprives applicants of their valuable rights under 35 U.S.C. § 120 to an unlimited number of continuation and continuation-in-part applications as a matter of right." Id. at 815.

We agree with the district court that Final Rule 78 is inconsistent with § 120, although we rely on narrower grounds. Section 120 unambiguously states that an application that meets four requirements "shall have the same effect, as to such invention, as though filed on the date of the prior application." 35 U.S.C. § 120 (emphasis added). These requirements, which correspond to the bracketed enumeration above, include [1] the invention claimed in the application must have been properly disclosed in a prior-filed application; [2] the application must have been filed by inventor(s) named on the prior-filed application; [3] the application must have been "filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application"; and [4] the application must contain or be amended to contain a specific reference to the prior-filed application. The use of "shall" indicates that these

are the exclusive requirements, and that all applications that meet these requirements must receive the benefit provided by § 120. See Transco Prods., Inc. v. Performance Contracting, Inc., 38 F.3d 551, 556 (Fed. Cir. 1994) ("The plain and unambiguous meaning of section 120 is that any application fulfilling the requirements therein 'shall have the same effect' as if filed on the date of the application upon which it claims priority."). Thus, Rule 78 is invalid because it attempts to add an additional requirement—that the application not contain amendments, arguments, or evidence that could have been submitted earlier—that is foreclosed by the statute. Because the statute is clear and unambiguous with respect to this issue, the USPTO's reliance on Chevron and Brand X is unavailing.

As amici, several intellectual property and administrative law professors argue that Henriksen expressly recognized ambiguity in § 120. Accordingly, they argue, the USPTO's interpretation is entitled to deference under Brand X. We agree that the Henriksen court's approach of delving into the legislative history, which it noted was "somewhat inconclusive," indicates that the text of the statute contains some ambiguity. See Henriksen, 399 F.2d at 256-58. However, the issue in Henriksen was whether there was a "limit to the number of prior applications through which a chain of copendency may be traced to obtain the benefit of the filing date of the earliest of a chain of copending applications." Id. at 254. In other words, the question related to the permissible length of a chain of serial continuation applications, not the total number of continuation applications that may be filed. Specifically, the dispute was over the meaning of clause [3b] identified above—"an application similarly entitled to the benefit of the filing date of the first application." Id. at 260-61. The ambiguity in clause [3b],

however, cannot save Final Rule 78. The Final Rule limits continuation applications on the basis of the total number of such applications previously filed, not on the length of a given serial chain of such applications. 37 C.F.R. § 1.78(d)(1)(i)(B). By its terms, Final Rule 78 would apply to an applicant who seeks to file three continuation applications while the first application is still pending, even though each of these applications falls squarely within clause [3a] and would thus satisfy any reasonable interpretation of clause [3] and the rest of § 120. Therefore, while we must defer to the USPTO's reasonable interpretation of clause [3], there is no such interpretation that preserves the validity of Final Rule 78.

Finally, the USPTO's reliance on In re Bogese, 303 F.3d 1362 (Fed. Cir. 2002), is unavailing. In Bogese, this court affirmed the Board of Patent Appeals and Interferences's rejection of claims in the applicant's continuation application on the grounds of extraordinary delay in prosecution. 303 F.3d at 1366. The applicant had submitted "twelve continuation applications over an eight-year period and did not substantively advance prosecution of [the application at issue] when required and given an opportunity to do so." Id. at 1369. According to the USPTO, Bogese "forecloses any argument that the conditions enumerated in Section 120 for making a priority claim are exclusive." USPTO Br. 45. This is so, it contends, because the opinion recognized that "[t]he PTO has inherent authority to govern procedure before the PTO, and that authority allows it to set reasonable deadlines and requirements for the prosecution of applications." Bogese, 303 F.3d at 1368. We do not read the opinion so broadly. The holding of Bogese was that "the PTO has authority to order forfeiture of rights for unreasonable delay." Id. at 1369. However, Bogese does not extend that power

beyond the boundaries of prosecution history laches, which was upheld as an equitable defense to infringement in Symbol Technologies, Inc. v. Lemelson Medical, 277 F.3d 1361 (Fed. Cir. 2002) ("Symbol II"). Rather, the panel recognized that "the PTO has the authority to reject patent applications for patents that would be unenforceable under our holding in [Symbol II]." Bogese, 303 F.3d at 1367. We agree that the USPTO has "inherent authority to govern procedure before the PTO, and that authority allows it to set reasonable deadlines and requirements for the prosecution of applications." Id. at 1368. However, under Bogese, the USPTO cannot set requirements that conflict with § 120 unless those requirements comport with a proper application of prosecution history laches. There are no "firm guidelines" for determining when prosecution laches exists. Symbol Techs., Inc. v. Lemelson Med. Educ. & Research Found., 422 F.3d 1378, 1385 (Fed. Cir. 2005) ("Symbol IV"). However, it is limited to cases of "unreasonable and unexplained delay in prosecution." Id. at 1384-85. We need not address the precise boundaries of the USPTO's authority to promulgate rules under Bogese because Final Rule 78 is far too restrictive to fall within the scope of prosecution history laches. The rule operates on an applicant's third continuation application without regard to when it was filed, even if the delay is significantly shorter than any of the delays in our prior prosecution history laches cases. See, e.g., Symbol IV, 422 F.3d at 1386 (eighteen to thirty-nine years elapsed between filing and issuance); Bogese, 303 F.3d at 1369 (eight years without the applicant substantively advancing prosecution). The rule simply captures too many applications that would not be even remotely susceptible to a prosecution history laches challenge. Therefore,

Final Rule 78 is not a proper use of the USPTO's authority under Bogese to apply prosecution history laches.

2. Final Rule 114

The district court found that Final Rule 114, which governs the availability of RCEs, conflicts with the Patent Act in two ways. The first was that it "places a limit on RCEs as of right on the basis of application family, rather than on the basis of each individual application, whether it be a parent application or a continuation or continuation-in-part application." Tafas II, 541 F. Supp. 2d at 815. The district court found that this was inconsistent with 35 U.S.C. § 132, which uses the singular form of "application." Additionally, the court noted Congress's "pronouncement, upon enacting Section 132(b), that the RCE provisions 'shall apply to all applications' filed on or after June 8, 1995." Id. (quoting American Inventors Protection Act of 1999, Pub. L. No. 106-113, § 4405(b)(1), 113 Stat. 1501, 1501A-560 to 1501A-561 (1999)). Second, the court found that § 132(b)'s mandate that "[t]he director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant" gave applicants the right to "an unlimited number of RCEs per application at their discretion." Id. This right, the court held, was violated by Final Rule 114. Id.

We do not find that § 132 unambiguously dictates that its provisions be applied on a per application basis. Cf. Henriksen, 399 F.2d at 258 ("So read, 'an application' does not necessarily refer only to a single application."); 1 U.S.C. § 1 ("[W]ords importing the singular include and apply to several persons, parties, or things . . . ."). Therefore, because we defer to the USPTO's reasonable interpretation of the statute,

we conclude that Final Rule 114 can properly be applied on a per family basis. See Cooper Techs., 536 F.3d at 1337-38.

Appellees next argue that the use of "shall" in conjunction with the phrase "at the request of the applicant" in § 132(b) clearly shows that Congress intended RCEs to be unlimited and subject only to the applicant's discretion. GlaxoSmithKline Br. 40. We do not find the statute so clear. It is plausible that, as the USPTO suggests, § 132(b) simply directs the USPTO to "prescribe regulations" to govern the applicant's ability to request continued examination which must, in some circumstances, be granted. Under this reading, nothing prevents the USPTO from limiting the availability of the second and subsequent RCEs. Because § 132(b) does not unambiguously require the USPTO to grant unlimited RCEs, we defer to the USPTO's interpretation. See Cooper Techs., 536 F.3d at 1337-38.

Finally, Appellees argue that § 132(a) requires the USPTO to continue examination if "the applicant persists in his claim for a patent." Tafas Br. 32-33. Section 132(a) provides:

> Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined. No amendment shall introduce new matter into the disclosure of the invention.

35 U.S.C. § 132(a) (emphases added). The USPTO responds that this argument "reflects a misunderstanding of the relationship between subsections (a) and (b) [of § 132]." USPTO Br. 53. According to the USPTO, "[s]ubsection (a) provides for the

'reexamination' of an application at the applicant's request after the initial examination provided in section 131. In contrast, 'continued examination' under subsection (b) occurs after the reexamination provided for in subsection (a) is complete." Id. Section 132 does not define the difference between "continued examination" and "reexamination." Because we find the USPTO's explanation reasonable, we defer to its interpretation that § 132(a) does not require it to grant unlimited RCEs. See Cooper Techs., 536 F.3d at 1337-38. Under this interpretation, Final Rule 114 does not conflict with § 132(a).

3. Final Rules 75 and 265

The district court held that the ESD requirement violated 35 U.S.C. §§ 102, 103, 112, and 131, as well as this court's precedent that holds that applicants have no duty to search the prior art. The court began its analysis with § 112, ¶ 2's requirement that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." The district court held, and Appellees argue on appeal, that this language precludes the USPTO from putting an arbitrary limit on the number of claims in an application.

Subject to the arguable requirement that an applicant cannot "obscure" his invention by "undue multiplicity," our precedent does not suggest that there is a limit on the number of claims. In re Clark, 97 F.2d 628, 631 (CCPA 1938); see also In re Wakefield, 422 F.2d 897, 900 (CCPA 1970) ("[A]n applicant should be allowed to determine the necessary number and scope of his claims . . . ."); In re Chandler, 319 F.2d 211, 225 (CCPA 1963) ("[A]pplicants should be allowed reasonable latitude in stating their claims in regard to number and phraseology employed. The right of

applicants to freedom of choice in selecting phraseology which truly points out and defines their inventions should not be abridged."). However, we need not decide whether the USPTO may impose a limit on the number of claims an applicant can pursue because we do not find that the ESD requirement creates any such limit. Rather, it simply requires that an ESD be submitted if more than five independent or twenty-five total claims are included in certain sets of copending applications. Because we cannot, as discussed above, conclude that Final Rules 75 and 265, on their face, effectively foreclose applicants from successfully submitting ESDs, we similarly cannot conclude that these rules place an absolute limit on claim numbers in violation of § 112, ¶ 2.

The district court also found that Final Rules 75 and 265 went too far by requiring applicants to "conduct a broad search of patents, patent applications, and literature, and provide, among other things, a 'detailed explanation' of 'how each of the independent claims is patentable over the cited references.'" Tafas II, 541 F. Supp. 2d at 816 (quoting 37 C.F.R. § 1.265(a)). The court relied on several of this court's inequitable conduct cases that noted that, in general, there is "no duty to conduct a prior art search." Frazier v. Roessel Cine Photo Tech., Inc., 417 F.3d 1230, 1238 (Fed. Cir. 2005) (quoting FMC Corp. v. Hennessy Indus., Inc., 836 F.2d 521, 526 n.6 (Fed. Cir. 1987)); see also Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348, 1351 n.4 (Fed. Cir. 2005). We agree with the USPTO that these cases do not speak to whether the USPTO may impose such a duty by regulation. Indeed, this court has already upheld the USPTO's authority to require from applicants "such information as may be reasonably necessary to properly examine or treat the matter."

37 C.F.R. § 1.105; see also Star Fruits, 393 F.3d at 1282-84. On this record, we see no persuasive reason to prohibit the USPTO from requesting the information required by Final Rule 265, even if the applicant must take action to acquire that information.

Finally, the district court found that Final Rules 75 and 265 improperly shift the burden away from the examiner and onto the applicant. Tafas II, 541 F. Supp. 2d at 817. The court relied on the language in § 102 that "[a] person shall be entitled to a patent unless," along with the requirement in § 131 that "[t]he director shall cause an examination to be made of the application." Id. Additionally, the district court noted that this court's precedent places the burden of putting forth a prima facie case of unpatentability on the USPTO. See In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992). We agree with the district court that the USPTO bears the initial burden of proving unpatentability, but disagree that the ESD requirement shifts that burden. Final Rules 75 and 265 do not require an applicant to make a prima facie case of patentability. While the rules require an applicant to conduct a prior art search and report his view of why the invention is patentable based on the results, the content of this disclosure does not change the standards by which the application is examined. An examiner cannot reject an application because he believes that the applicant failed to find the most material references or if he is otherwise not persuaded by the applicant's view of the prior art. Even under the new rules, the examiner must examine the application in accordance with § 131 and the applicant will be "entitled to a patent unless" the examiner can make a prima facie case of unpatentability. 35 U.S.C. § 102. Thus, while creating an additional procedural step for the submission of applications,

the ESD requirement does not alter the ultimate burdens of the examiner or applicant during examination.

III. CONCLUSION

For the foregoing reasons, we conclude that the Final Rules 75, 78, 114, and 265 are procedural rules that are within the scope of the USPTO's rulemaking authority. However, we find that Final Rule 78 conflicts with 35 U.S.C. § 120 and is thus invalid. Accordingly, we affirm the district court's grant of summary judgment that Final Rule 78 is invalid, vacate its grant of summary judgment with respect to Final Rules 75, 114, and 265, and remand for further proceedings consistent with this opinion.

Because of the complexity of this case and the numerous arguments presented on appeal and before the district court, we think it is important to expressly summarize what we believe remains for the district court on remand. This opinion does not decide any of the following issues: whether any of the Final Rules, either on their face or as applied in any specific circumstances, are arbitrary and capricious; whether any of the Final Rules conflict with the Patent Act in ways not specifically addressed in this opinion; whether all USPTO rulemaking is subject to notice and comment rulemaking under 5 U.S.C. § 553; whether any of the Final Rules are impermissibly vague; and whether the Final Rules are impermissibly retroactive.

COSTS

Each party shall bear its own costs.

AFFIRMED-IN-PART, VACATED-IN-PART, AND REMANDED

United States Court of Appeals for the Federal Circuit

2008-1352

TRIANTAFYLLOS TAFAS,

Plaintiff-Appellee,

and

SMITHKLINE BEECHAM CORPORATION (doing business as GlaxoSmithKline),
SMITHKLINE BEECHAM PLC, and
GLAXO GROUP LIMITED (doing business as GlaxoSmithKline),

Plaintiffs-Appellees,

v.

JOHN J. DOLL, Acting Under Secretary of Commerce for Intellectual Property
and Acting Director of the United States Patent and Trademark Office,
and UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendants-Appellants.

Appeal from the United States District Court for the Eastern District of Virginia in consolidated case nos. 1:07-CV-846 and 1:07-CV-1008,
Senior Judge James C. Cacheris.

BRYSON, Circuit Judge, concurring.

I join Judge Prost's opinion but with the following observations.

1. In my view, the question whether the PTO is authorized to promulgate particular regulations does not turn on an abstract inquiry into whether a particular rule can be characterized as substantive, procedural, or interpretive. Instead, it calls on us to ask what Congress has empowered the PTO to do through rulemaking. Congress has not used the broadest available language in the statute that authorizes the PTO to engage in rulemaking, but neither has it used the narrowest. Congress could have

authorized the PTO to issue any regulations that are necessary or appropriate to administer the patent laws. See, e.g., 38 U.S.C. § 501 (Secretary of Veterans Affairs authorized to prescribe "all rules and regulations which are necessary or appropriate to carry out the laws administered by the Department"); 5 U.S.C. § 8347(a) (Office of Personnel Management given authority to prescribe "such regulations as are necessary and proper to carry out [the Civil Service Retirement Act]"). Language of that sort would have given the PTO the very broad rulemaking authority. On the other hand, the PTO could have given no special authority to promulgate regulations, which would have had the effect of limiting the PTO to the narrow scope of 5 U.S.C. § 301, which allows all agencies to prescribe regulations "for the government of . . . [the] department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property." Congress did neither. Instead, it charted a middle course in 35 U.S.C. § 2(b), permitting the agency somewhat broader regulatory powers than are contemplated by section 301, but narrower than the broad "necessary or appropriate" rulemaking authority given to some other agencies.

Section 2(b)(2)(A) of the Patent Act vests the PTO with authority to promulgate regulations that "govern the conduct of proceedings in the Office." The subject matter that most clearly falls within the scope of that provision is the admission and discipline of attorneys practicing before the PTO. See, e.g., Bender v. Dudas, 490 F.3d 1361, 1368 (Fed. Cir. 2007); Lacavera v. Dudas, 441 F.3d 1380, 1383 (Fed. Cir. 2006). Even apart from that context, however, we have taken a fairly expansive view of the scope of section 2(b)(2)(A). For example, in In re Sullivan, we held that section 2(b)(2)(A)

authorized the PTO to promulgate a regulation permitting conferences between an administrative patent judge and the parties to an interference proceeding. 362 F.3d 1324, 1328 (Fed. Cir. 2004). Also in the interference context, we held in Stevens v. Tamai that the PTO acted within its authority under section 2(b)(2)(A) when it promulgated regulations establishing that the movant has the burden of proof and duty of translating earlier filed documents into English, so as to show that the international application contains the same disclosure as the national stage application. 366 F.3d 1325, 1332 (Fed. Cir. 2004). Finally, in Cooper Technologies Co. v. Dudas, we held that the PTO was entitled to promulgate a regulation defining the term "original application" in a statutory provision that established the procedures for inter partes reexamination, and that the regulation was entitled to Chevron deference. 536 F.3d 1330, 1336-38 (Fed. Cir. 2008).

For essentially the reasons given by the majority opinion and in light of the above-cited authorities, I am satisfied that the regulations in this case are of the type that Congress authorized in section 2(b) of the Patent Act, as that provision has been construed by this court. While I think it is generally fair to characterize that statute as authorizing the promulgation of "procedural" regulations, however, I do not think it necessary, or particularly helpful, to consider whether those regulations would be deemed "substantive," "interpretive," or "procedural" either under section 4 of the Administrative Procedure Act, 5 U.S.C. § 553, or under statutory schemes applicable to other agencies.

The same approach seems to me to be called for in deciding whether the agency is entitled to deference with respect to the scope of its own authority. There, too, the

issue comes down to one of statutory construction—whether Congress left the boundaries of agency authority undefined and subject to refinement through the exercise of agency expertise, or whether Congress established a firm line, enforceable by courts, beyond which the agency could not venture. Normally, Congress defines the field of agency rulemaking authority in unambiguous terms that are readily applied by courts, so there is little reason to resort to Chevron-type analysis. In some instances, however, Congress has defined the agency's rulemaking jurisdiction using vague terms, or terms that call for agency interpretation, or even terms that expressly leave the scope of rulemaking authority to the agency to decide; in those cases, deference to the agency may be appropriate or even necessary. See, e.g., Bender v. Dudas, 490 F.3d 1361, 1368 (Fed. Cir. 2007) (deference given to PTO's interpretation of the phrase "before the Office" in section 2(b)(2)); Enercon GmbH v. Int'l Trade Comm'n, 151 F.3d 1376, 1380-81 (Fed. Cir. 1998) (deference given to ITC's interpretation of the word "sale" in the statute giving it jurisdiction, 15 U.S.C. § 1337); 5 U.S.C. § 7701(a) (authorizing Merit Systems Protection Board to act on appeals authorized by "any law, rule, or regulation"). In this case, it is unnecessary to decide whether deference would be due to the agency's interpretation of its own authority, as we conclude, even without deference, that the agency has authority to issue regulations of the sort issued in this case, subject to their consistency with the underlying statutory provisions being interpreted.

Because I agree with Judge Prost that the challenged regulations are within the scope of the authorization that Congress granted to the PTO in section 2(b), I likewise

conclude that the issue in this case comes down to whether the challenged regulations are consistent with other provisions of the Patent Act.

2. On the merits, the most difficult question in this case for me is whether Final Rule 78 is a valid regulation in light of 35 U.S.C. § 120. My colleagues conclude that it is invalid, although for different reasons. I agree that it is invalid for the reasons given by Judge Prost, although I think it is important to emphasize the narrow scope of the court's decision.

The court holds that Final Rule 78 is invalid because it limits the number of continuation applications that may be filed and applies that limit even if all of the continuation applications are filed while the first application is still pending. Section 120 plainly provides that any application that satisfies the other requirements of the statute and is "filed before the patenting or abandonment of or termination of proceedings on the first application" shall have the same effect "as though filed on the date of the prior application." 35 U.S.C. § 120. Therefore, a rule limiting the number of continuances co-pending with the first-filed application is necessarily contrary to the statute and invalid.

While that is a sufficient reason to invalidate Final Rule 78, it does not answer the question whether the rule is invalid as applied to serial continuances, i.e., a series of continuances in which each was co-pending with its immediate predecessor, but in which only the second in the series was co-pending with the first application. Under current law, all continuances in such a series, if they satisfy the other requirements of section 120, are deemed to have the same effective date as the first application. Rule 78 would change that practice.

The question whether the new Rule's restrictions on serial continuances would also be invalid is more complex than the question of the validity of restrictions on co-pending applications. As to serial continuances, section 120 provides that an application for continued prosecution is entitled to the benefit of an earlier priority date when it is co-pending with "an application similarly entitled to the benefit of the filing date of the first application." For the last 40 years, that portion of section 120 has been understood to confer upon patent applicants the right to file any number of successive continuation applications after the first application has been abandoned or issued as a patent. That was the construction of section 120 that our predecessor court adopted in 1968, overturning a Patent Office Board of Appeals decision to the contrary. In re Henriksen, 399 F.2d 253, 254 (CCPA 1968). It would not be unreasonable, however, to construe the phrase "an application similarly entitled" to mean an application that satisfies all the preceding requirements set forth in section 120, including the requirement of co-pendency with the initial application, which was the construction adopted by the Patent Office Board of Appeals in the Henriksen case. See Ex parte Henriksen, 154 U.S.P.Q. 53 (1966). In fact, the court in Henriksen acknowledged that a literal reading of the statutory language would lead to that conclusion. In re Henriksen, 399 F.2d at 256, 260-61 & n.18. Under that interpretation, applicants would be limited to a maximum of two continuations in series—one while the first application is pending and another while the first continuation is pending. Because the term "similarly entitled" admits of two reasonable constructions, the PTO could have adopted the narrower construction notwithstanding prior judicial precedent construing the statute in the

absence of a regulation interpreting the statutory language. See Nat'l Cable & Telecomms. Assn' v. Brand X Internet Servs., 545 U.S. 967, 982-86 (2005).

The court today properly strikes down Final Rule 78 because its restrictions on co-pending, or parallel, continuations is contrary to the plain language of section 120, which provides that such a co-pending continuation "shall" be given the same priority date as the original application and which contains no restriction on the numbers of such applications that are permitted. That is not to say, however, that a revised rule that addressed only serial continuances and limited such continuances to only two—the first co-pending with the original application and the second co-pending with the first—would be struck down as reflecting an impermissible interpretation of section 120. That is not a question that we need to—or should—decide today, but in my view it is important to emphasize that the question remains open.

United States Court of Appeals for the Federal Circuit

2008-1352

TRIANTAFYLLOS TAFAS,

Plaintiff–Appellee,

and

SMITHKLINE BEECHAM CORPORATION (doing business as GlaxoSmithKline),
SMITHKLINE BEECHAM PLC, and
GLAXO GROUP LIMITED (doing business as GlaxoSmithKline),

Plaintiffs–Appellees,

v.

JOHN J. DOLL, Acting Under Secretary of Commerce for Intellectual Property
and Acting Director of the United States Patent and Trademark Office,
and UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendants–Appellants.

Appeal from the United States District Court for the Eastern District of Virginia in consolidated case nos. 1:07-CV-846 and 1:07-CV-1008, Senior Judge James C. Cacheris.

RADER, Circuit Judge, concurring in part and dissenting in part.

I concur with this court's conclusion that the PTO is not entitled to Chevron deference with respect to its own rulemaking authority. However, in my view, the Final Rules are substantive, not procedural. Thus, I would affirm the district court's conclusion that the PTO exceeded its statutory rulemaking authority in promulgating these rules. For that reason, I concur in part with this court's ultimate conclusion regarding Final Rule 78, but dissent in part with respect to Final Rules 114, 75, and 265.

I

This case presents a threshold question about the nature of these rules—substantive or procedural. The organic act of the PTO "does NOT grant the Commissioner the authority to issue substantive rules." Merck & Co. v. Kessler, 80 F.3d 1543, 1550 (Fed. Cir. 1996) (emphasis in original). Unlike grants of rulemaking authority to many other administrative agencies, the PTO does not enjoy substantive rulemaking authority. Accordingly, the legislative branch has retained the responsibility for developing substantive patent law. To the extent that the PTO's Final Rules are substantive, this court cannot permit the PTO to exceed its authority.

The distinction between substantive or non-substantive rules requires a difficult judgment. This distinction arises most often in the context of interpreting the exception to the requirement for notice and comment procedures in the Administrative Procedure Act ("APA"). 5 U.S.C. § 553(b)(A). In the most common scenario, an agency has promulgated a rule without undergoing the strictures of notice and comment rulemaking. The reviewing court must then, when necessary, apply the APA's exemption for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." Id. In other words, the courts may only sustain non-substantive rulemaking in those cases. See, e.g., Animal Legal Def. Fund v. Quigg, 932 F.2d 920 (Fed. Cir. 1991); JEM Broad. Co. v. FCC, 22 F.3d 320 (D.C. Cir. 1994); Am. Hosp. Ass'n v. Bowen, 834 F.2d 1037 (D.C. Cir. 1987). These cases have set forth a balancing test to identify a non-substantive rule: a rule is sufficiently non-substantive "where the policies promoted by public participation in rulemaking are outweighed by the countervailing considerations of effectiveness, efficiency, expedition

and reduction in expense." Guardian Fed. Sav. & Loan Ass'n v. Fed. Sav. & Loan Ins. Corp., 589 F.2d 658, 662 (D.C. Cir. 1978).

The instant case, however, presents a different situation. These PTO rules have no procedural defects. Instead, this case asks this court to ensure that the PTO has not exceeded its rulemaking authority. Thus, in the present context, this court misapplies the teachings of cases such as Animal Legal Defense Fund and Cooper Technologies Co. v. Dudas, 536 F.3d 1330 (Fed. Cir. 2008). These cases focus on the distinction between "interpretative" and "substantive" rules. Parsing the difference between "interpretive," "procedural," and "policy" rules may be relevant in the context of categorizing a rule into one of the APA's exceptions to notice and comment rulemaking, but has no relevance to the question of exceeding a grant of rulemaking authority. In the unique context of this case, it makes no sense to classify a rule as "procedural" or "interpretative." Either of those labels leads to the same conclusion—that the rule is non-substantive. See Cooper Techs., 536 F.3d at 1336 (finding the PTO's interpretation of "original application" in 35 U.S.C. § 4608 to be "procedural" within the meaning of 35 U.S.C. § 2(b)(2) because it was "'interpretative' . . . rather than 'substantive'"); see also Animal Legal Def. Fund, 932 F.2d at 927 (contrasting "substantive" rules with the general category of "exempt 'interpretative' rules of section 553(b)"). Thus, I would not so casually discard, as this court does today, this court's precedent for identifying a "substantive" rule.

The Supreme Court provided valuable guidance on the substantive/non-substantive inquiry in Chrysler Corp. v. Brown, 441 U.S. 281 (1979). In Chrysler, the Court defined an inherent characteristic of a "substantive" or "legislative-type" rule,

namely, such rules "affect[ ] individual rights and obligations." Id. at 302. Contrary to this court's analysis today, the Chrysler Court's reasoning was in no way limited to defining the boundary between interpretative and substantive rules. The Court sought to draw a broad distinction between substantive and non-substantive rules—the same inquiry presented in this case. Id. Shedding light on this distinction, the Court recognized that "[a] 'substantive rule' is not defined in the APA," but that the term is best defined by "negative inference." Id. at 301-02 (emphasis added). Put differently, a rule is "substantive" if it is not an "interpretive rule[ ], general statement[ ] of policy, or rule[ ] of agency organization, procedure, or practice." Id. at 301.

Both this court and the Court of Appeals for the District of Columbia Circuit have relied on Chrysler in building a body of jurisprudence germane to the substantive/non-substantive inquiry. Central to this jurisprudence is the recognition that classifying a rule as substantive or non-substantive is a case-by-case exercise, poorly suited for bright-line rules. See, e.g., Bowen, 834 F.2d at 1045 ("Determining whether a given agency action is interpretive or legislative is an extraordinarily case-specific endeavor . . . . [A]nalogizing to prior cases is often of limited utility in light of the exceptional degree to which decisions in this doctrinal area turn on their precise facts."); Chamber of Commerce v. Dep't of Labor, 174 F.3d 206, 212 (D.C. Cir. 1999) ("[T]he question whether a rule is substantive or procedural for the purposes of § 553(b) is functional, not formal.").

No doubt, the Chrysler Court's inquiry—whether a rule "affects individual rights and obligations"—if analyzed in a vacuum, would blur the line between substantive and non-substantive rules. See, e.g., Bowen, 834 F.2d at 1046 ("[T]he mere fact that a rule

may have a substantial impact does not transform it into a legislative rule."); Neighborhood TV Co. v. FCC, 742 F.2d 629, 637 (D.C. Cir. 1984) ("[E]very change in rules will have some effect on those regulated.") (internal quotation marks omitted). For this reason, as the D.C. Circuit stated in JEM, the "critical feature" of a procedural, non-substantive rule is that "it covers agency actions that do not themselves alter the rights or interests of parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency." JEM, 22 F.3d at 326. Although the court's opinion today seizes upon this instructive language from JEM, it sadly overlooks JEM's ensuing statement: "[t]he issue, therefore, is one of degree . . . our task is to identify which substantive effects are sufficiently grave . . . ." Id. at 327 (emphases added) (internal quotation marks omitted). Assessing the challenged FCC rule's impact, which merely curtailed "a license applicant's right to a free shot at amending its application," the court in JEM concluded that the rule was "not so significant" as to be classified as substantive. Id. (emphasis added). Thus, as JEM illustrates, the test for substantive, ultra vires rules is a case-by-case inquiry, not a rigid application of a sentence out of context in JEM.

To my eyes, this question of degree must guide this court's assessment of the substantive nature of the PTO's Final Rules. This court has confronted that question before and gauged a rule's impact on parties' rights and obligations by examining the rules' changes to existing law or policy. See, e.g., Cooper Techs., 536 F.3d at 1336; Animal Legal Def. Fund, 932 F.2d at 927. The D.C. Circuit has also adopted this language as relevant to the inquiry. See, e.g., Bowen, 834 F.2d at 1045 ("Substantive rules are ones which grant rights, impose obligations, or produce other significant

effects on private interests, or which effect a change in existing law or policy.") (internal citations and quotation marks omitted). For example, in Cooper Technologies, this court held that a PTO rule giving effect to the term "original application" was non-substantive because it "does not effect any change in existing law or policy; rather, it is a prospective clarification of ambiguous statutory language regarding a matter of procedure." 536 F.3d at 1336. Similarly, in Bowen, a manual promulgated by the Department of Health and Human Services was a "classic procedural rule[]" because, in mapping out an enforcement strategy for third party contractors, it "impose[d] no new burdens on hospitals." Bowen, 834 F.2d at 1050-51.

The D.C. Circuit's 1999 decision in Chamber of Commerce is particularly instructive. 174 F.3d at 206. In that case, the court considered a new directive promulgated by the Occupational Safety and Health Administration ("OSHA") establishing a new compliance program for dangerous workplaces. Id. at 208. The Directive provided that the agency would reduce the probability of an onerous inspection if a workplace implemented a so-called comprehensive safety and health program ("CSHP"). Id. Although "[m]ost of the [CSHP] requirements are procedural," the Directive was clear that compliance with the Occupational Safety and Health Act was "not in itself sufficient" for compliance with the newly promulgated CSHP. Id. Plaintiffs challenged the Directive on the ground that it was a substantive rule, and OSHA had not undergone the requisite notice and comment procedures. Id. at 209. The court agreed with the plaintiffs, holding that the rule was substantive "[a]t least to the extent that participation in the CCP requires more than adherence to existing law . . . ." Id. at 211 (emphasis added). Indeed, because the Directive imposed upon

employers "more than the incidental inconveniences of complying with an enforcement scheme," it was plainly substantive. Id. at 211-12 (internal quotation marks omitted).

Implicit in the majority's holding that the Final Rules are procedural is that the rules fit within the "procedural" exception to the APA's notice and comment requirement. Yet applying this logic, the PTO would never be subject to the APA's notice and comment procedures because it only has statutory authority to promulgate rules that fall within exceptions to notice and comment, i.e., non-substantive rules. Here, the PTO provided a notice and comment period. In other words, the PTO recognized that "the policies promoted by public participation in rulemaking . . . outweigh[ed] . . . countervailing considerations of effectiveness, efficiency, expedition and reduction in expense." See Guardian Federal, 589 F.2d at 662 (providing that notice and comment is not required when these "countervailing considerations trump public participation"). The public participation during that period was overwhelming (itself an indication of the substantive impact of the rules?). Many of the comments shared a common concern: that the Final Rules "had a significant effect on private interests, and marked a change in existing law or policy." I share that concerned view.

II

Contrary to this court's holding today, the Final Rules are not "incidental inconveniences of complying with an enforcement scheme." The Final Rules are substantive. The Final Rules affect individual rights and obligations, and mark a startling change in existing law and patent policy. As the district court correctly noted,

> The 2+1 Rule and the 5/25 Rule, which limit continuing applications, RCEs, and claims, and the ESD requirement, which shifts the examination burden onto applicants, constitute a drastic departure from the terms of the Patent Act as they are presently understood. By so departing, the

> Final Rules effect changes in GSK's and Tafas's existing rights and obligations.

Tafas v. Dudas, 541 F. Supp. 2d 805, 814 (E.D. Va. 2008) (emphasis added). I will briefly consider each Final Rule in turn.

A. Final Rule 78

Final Rule 78 restricts to two the number of continuation applications entitled to an earlier priority date, unless the applicant files a petition showing that the amendment, argument, or evidence could not have been submitted during the prosecution of the prior-filed application ("petition and showing"). As this court notes today, that rule contravenes the language of 35 U.S.C. § 120. The statute is clear: later filed continuation applications "shall have the same effect, as to such invention, as though filed on the date of the prior application." 35 U.S.C. § 120 (emphasis added). Final Rule 78 is not "a prospective clarification of ambiguous statutory language regarding a matter of procedure," Cooper Techs., 536 F.3d at 1336, because the statute mandates that continuations "shall have the same effect." Section 120 creates a substantive right to claim the earlier priority date in later-filed continuation applications.

In fact, this court's predecessor considered the language of 35 U.S.C. § 120: "[T]here is no statutory basis for fixing an arbitrary limit to the number of [continuing] applications" that can retain the benefit of the priority date. In re Henriksen, 399 F.2d 253, 254 (CCPA 1968). The court recognized that placing "a limit upon continuing applications is a matter of policy for the Congress." In re Hogan, 559 F.2d 595, 604 n.13 (CCPA 1977). In other words, Final Rule 78 attempts to usurp legislative prerogatives. If the Act contemplated a limit on the number of continuation applications

available as a matter of right, then a limitation to that effect would appear in § 120. Instead § 120 says the opposite.

The Office argues that Final Rule 78 is not substantive because the petition and showing requirement provides an alternative avenue for seeking additional continuations. The PTO's argument admits far too much. In order to receive the benefit of priority for later-filed continuation applications, which was previously available as a matter or right, the applicant must now justify the right with further showings. This new "petition and showing" hurdle is neither required nor contemplated by § 120. In mechanically applying only one statement from JEM, the majority opinion ignores that the "substantive effect" of failing to meet this new obligation—the loss of priority date—is "sufficiently grave" to make this rule substantive. See JEM, 22 F.3d at 327.

B. Final Rule 114

The same holds true with respect to Final Rule 114, imposing a limit of one request for continued examination ("RCE") per application family. The American Inventor's Protection Act of 1999 stated that the RCE provisions "shall apply to all applications" filed on or after June 8, 1995. The Act did not impose or contemplate a restrictive RCE practice. To the contrary, subject to the doctrine of prosecution laches, applicants could file an RCE as a matter of right.

The impact and reach of the Final Rules 78 and 114 ("the 2+1 Rule") significantly affects patent prosecution. Several amicus briefs point out reasonable scenarios where an applicant may choose to file an RCE during prosecution, e.g., in order to provoke an interference, to clarify claim scope in anticipation of litigation, and to submit an

information disclosure statement ("IDS"). Yet these Final Rules could interfere with those reasonable scenarios.

By way of example, consider the following scenario: An applicant receives a Notice of Allowance for application A. Before paying the issue fee, the applicant discovers a material prior art reference in a foreign application. Mindful of the duty to disclose material information to the Office, that applicant would file an RCE, an IDS citing the reference, and an amendment to account for the newly discovered prior art. So far so good, but what if the reference is not only material to application A, but also material to continuation applications B and C, members of the same application family that have also received Notices of Allowance? Under the 2+1 Rule, the applicant would have exhausted the two continuations and one RCE. What happens to applications B and C? Even if the submission of newly-discovered prior art satisfied the "petition and showing" requirement (which the PTO has said it will likely not), the "petition and showing" requirement is legislative because it imposes a new burden on the inventor. Because they require "more than adherence to existing law," Final Rules 78 and 114 are substantive. See Chamber of Commerce, 174 F.3d at 211.

C. Final Rule 75

Final Rule 75 limits an application to five independent claims or twenty-five claims total. Placing an arbitrary limit on the number of claims in an application drastically affects an applicant's rights and obligations under the Patent Act. To be specific, this rule alters obligations under 35 U.S.C. §§ 102, 103, 112, and 131. For instance, § 112, ¶ 2 requires that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the

applicant regards as his invention." 35 U.S.C. § 112, ¶ 2 (emphasis added). Placing a mechanical cap on the number of claims in an application hinders an applicant's right (and obligation) to "particularly [point] out and distinctly [claim] the subject matter which the applicant regards as his invention." Id. Indeed, "one or more claims" suggests at least one, not a ceiling to the number of claims in an application. Once again, if the Act wished to specify an upper limit on the number of claims, it could do so right at this point. Instead the "or more" requirement places no limit on the number of claims. The Act instead articulates a clear policy in favor of allowing as many claims as an applicant is willing to pay for.

As the majority opinion acknowledges, this court's precedent suggests no limit on the number of claims. See In re Wakefield, 422 F.2d 897, 900 (CCPA 1970) ("[A]n applicant should be allowed to determine the necessary number and scope of his claims . . . ."); In re Chandler, 319 F.2d 211, 225 (CCPA 1963) ("[A]pplicants should be allowed reasonable latitude in stating their claims in regard to number and phraseology employed. The right of applicants to freedom of choice in selecting phraseology which truly points out and defines their inventions should not be abridged."). This court should and does understand that some inventions are easier to describe, or lend themselves well to drawings. Others are more complicated and may take several iterations of claims in order to capture and fully disclose one's invention.

By analogy, this rule has a similar effect to imposing a five-page limit on applications. Although that notion is obviously too simplistic and problematic, this court's rationale would apparently make that hypothetical rule possible as a procedural

rule that merely "[alters] the manner in which the parties present themselves or their viewpoints to the agency." JEM, 22 F.3d at 326. To my eyes, much more is at stake.

Likewise, limiting an applicant to five independent claims ignores the varying scopes and methods of claiming inventions across different technologies. For example, in a pharmaceutical application, an applicant may claim not only the genus compound, but also a number of species, intermediates, methods of making, and methods of use. Asking an inventor to limit her application to five independent claims disproportionately affects technologies with greater complexity and greater public interest in disclosure. See Neighborhood TV, 742 F.2d at 637 ("In determining whether a rule is substantive, we must look at its effect on those interests ultimately at stake in the agency proceeding.").

This court today forgets that an inventor's incentive to disclose is commensurate with the protection available. With less ability to claim myriad methods of making, methods of use, species and intermediates, and more, an inventor will have less incentive to disclose the full dimension of the technological advance. Final Rule 75 frustrates the quid pro quo contemplated by the Patent Act.

D. Final Rule 265

On appeal, the PTO submits that limiting an application to five independent claims, or twenty-five claims total, is not a mechanical limitation, but just a trigger to the requirement to file an Examination Support Document ("ESD"). Final Rule 265 goes too far, however, by requiring an applicant to "conduct a broad search of patents, patent applications, and literature, and provide, among other things, a 'detailed explanation' of 'how each of the independent claims is patentable over the cited references.'" Tafas,

541 F. Supp. 2d at 816 (quoting 37 C.F.R. § 1.265(a)). Setting aside its onerous burden and its risk to cause later allegations of inequitable conduct, the ESD requirement improperly shifts the burden of proving patentability onto the applicant — a direct conflict with this court's interpretation of section 102.

Section 102 provides "[a] person shall be entitled to a patent unless" and section 131 provides that "[t]he director shall cause an examination to be made of the application." 35 U.S.C. §§ 102, 131. Thus, the PTO bears the burden of putting forth a prima facie case of unpatentability. See In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Indeed, this court has recognized that an applicant does not have the duty to perform a prior art search. Frazier v. Roessel Cine Photo Tech, Inc., 417 F.3d 1230, 1238 (Fed. Cir. 2005).

Although this court has upheld the PTO's authority to request "such information as may be reasonably necessary to properly examine or treat the matter," Star Fruits S.N.C. v. United States, 393 F.3d 1277, 1282 (Fed. Cir. 2005), Rule 105 relates to information that is already in the applicants' possession; it does not impose an affirmative duty to perform a prior art search or opine regarding patentability over the closest reference. See 37 C.F.R. § 1.105. In contrast, the ESD requirement places a new obligation on the inventor. The ESD is something more than supplying the Office with an English language translation or turning over information already in the applicant's possession. It shifts the burden of proving patentability onto the applicant.

This shift of the burden of proof (or production, for that matter) onto the applicant significantly alters practice before the PTO and represents "a change in existing law or policy." Animal Legal Def. Fund, 932 F.2d at 927. Satisfaction of the ESD requirement

requires "more than adherence to existing law" and amounts to "more than the incidental inconveniences of complying with an enforcement scheme." See Chamber of Commerce, 174 F.3d at 211-12. As such, Final Rules 75 and 265 are substantive.

III

Because the Final Rules drastically change the existing law and alter an inventor's rights and obligations under the Patent Act, they are substantive and the PTO exceeded its statutory rulemaking authority under 35 U.S.C. § 2(b)(2). For the reasons stated above, I would affirm.